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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/485,951	02/17/2000	SEISHI KATO	GI6707PCT-US	2545

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EXAMINER
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ART UNIT	PAPER NUMBER
1642	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/485,951	Applicant(s) Kato et al
	Examiner Karen Canella	Art Unit 1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3 months* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____.

2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *6-10 and 15-17* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *6-10 and 15-17* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Response to Amendment

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

2. Claims 11-14 have been canceled. Claims 7-9 have been amended. Claims 15-17 have been added. Claims 6-10 and 15-17 are pending and under consideration.

Claim Rejections Maintained

3. The rejections of Claims 6-10 under 35 U.S.C. 101 because the claimed invention is not supported by either a specific, substantial asserted utility or a well-established utility, is maintained for reasons of record. Newly added claims 15-17 are also rejected for the same reasons of record.

The rejection of claims 6-10 under 35 U.S.C. 112, first paragraph is maintained for reasons of record. Newly added claims 15-17 are also rejected for the same reasons of record.

Applicant argues that the invention is specific because the disclosed SEQ ID NO:2 binds lactose. Applicant further argues that the invention is substantial because other members of the galectin family are known to be involved in important biological processes such as cell adhesion, cell growth regulation, inflammation, imunomodulation, apoptosis and metastasis. This has been considered but not found persuasive. The binding of lactose is not considered specific as numerous carbohydrate binding proteins bind galactose. Further, the utility which is asserted to be specific must also be substantial, and the binding of lactose does not impart a substantial utility to the discloses polypeptide. Applicants have not asserted a specific activity of SEQ ID NO:2 that was also a credible and substantial activity.

Applicant argues that the instant galectin-9 would have an inherent utility based on being a member of the galectin family, said family members known to be involved in important biological processes requiring carbohydrate recognition such as cell adhesion, growth regulation, inflammation, immunomodulation, apoptosis and metastasis. However, as stated in the previous Office action, as the said other members of the galectin family bind lactose but exhibit widely different function, one cannot attribute a specific utility to the instant SEQ ID NO:2 based on membership in the galectin family. For example, galectin-1 induces apoptosis in T-cells and in T-

cell leukemia, while galectin-3 confers resistance to apoptosis in cultured cells. Further, comparison of SEQ ID NO:2 with as ecalectin (Matsumoto et al, Journal of Biological Chemistry, July 3, 1998, Vol. 273, pp. 16976-16984, Figure 1), indicates that the instant SEQ ID NO:2 is identical to ecalectin the exception of residues 149 to 180 of the instant sequence which are absent in ecalectin. Ecalectin is an eosinophil chemoattractant having a utility apart from apoptosis, growth regulation or metastasis. As the activities of the prior art galectins are diverse, including different sites of action and different functions, a specific, substantial and credible utility cannot be established for the instant invention based on membership in the galectin family.

New Claim Rejections

4. Claims 8 and 9 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Amendment of the claims to recite an "isolated" polypeptide would obviate this rejection..

5. Claims 7, 8, 10, 16 and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7 recites "An isolated polypeptide consisting of a fragment of a polypeptide comprising the amino acid sequence of SEQ ID NO:2, wherein the fragment comprises at least 30 contiguous amino acids of SEQ ID NO:2." The phrase "fragment of a polypeptide comprising the amino acid sequence of SEQ ID NO:2" states that the entire sequence of SEQ ID NO:2 is contained in said fragment. The following phrase "wherein the fragment comprises at least 30 contiguous amino acids sequences of SEQ ID NO:2" directly contradicts the meaning of the first phrase. As such the metes and bounds of the claim cannot be determined. For purpose of examination, the claim will be read as ---An isolated polypeptide comprising a fragment of SEQ ID NO:2, said fragment consisting of at least 30 contiguous amino acids of SEQ ID NO:2.---

Claim 8 recites "A naturally occurring allelic variant of a polypeptide comprising the amino acid of SEQ ID NO:2". It is not clear if the claim reads on an allelic variant comprising

SEQ ID NO:2 or if the claim reads on an allelic variant of SEQ ID NO:2. For purpose of examination the claim will be read as ---A polypeptide comprising a naturally occurring allelic variant of SEQ ID NO:2---.

The recitation of "isolated" in claims 16 and 17 lacks proper antecedent basis in claims 8 and 9.

6. Claims 7, 8, 9, 10, 16 and 17 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The written description in this case sets forth only the polynucleotide of SEQ ID NO:3 , and the amino acid sequence encoded thereby (SEQ ID NO:2) and a fragment consisting of residues 149 to 180 of SEQ ID NO:2 (SEQ ID NO:1) and therefore the written description is not commensurate in scope with the claims drawn to a polypeptide comprising a naturally occurring allelic sequences of SEQ ID NO:2, a polypeptide comprising at least 30 contiguous amino acid of SEQ ID NO:2, or a polypeptide which is 90% identical to a polypeptide comprising the amino acid sequence of SEQ ID NO:1 or 2.

Vas-Cath Inc. V. Mahurkar, 19 USPQ2d 1111, clearly states that applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the "written description" inquiry, whatever is now claimed. (See page 1117). The specification does not clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed. (See Vas-Cath at page 1116).

Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 U.S.C. 112 is severable from its enablement provision (see page 115).

Claim 8 is drawn to a polypeptide comprising a naturally occurring allelic variant of SEQ ID NO:2. Reiger et al (Glossary of Genetics and Cytogenetics, Classical and Molecular, 4th Ed., Springer-Verlay, Berlin, 1976) clearly define alleles as one of two or more alternative forms of a gene occupying the same locus on a particular chromosome.....and differing from other alleles of

that locus at one or more mutational sites (page 17). Thus, the structure of naturally occurring allelic sequences are not defined and no disclosure, beyond the mere mention of allelic variants is made in the specification.

Further claim 7 is drawn in part to isolated polypeptides comprising 30 amino acids of SEQ ID NO:2 and the claim does not recite a functional activity for the encompassed polypeptides. The specification discloses only a single species, SEQ ID NO:1, as a 32 residue amino acid fragment of SEQ ID NO:2 which is not present in the prior art disclosure of human Galectin 9. Clearly, a polypeptide comprising only 30 contiguous amino acids of SEQ ID NO:2 might not even be a member of the galectin family or have the ability to bind lactose as the disclosed SEQ ID NO:2. The specification does not teach a function for all the polypeptides encompassed in the broadly claimed genus.

Claim 9 is drawn to a polypeptide which is at least 90% identical to a polypeptide comprising the amino acid of SEQ ID NO:1 or 2. As such the claims are drawn to a genus of polypeptides that have no defined function and have not been described beyond the mere mention that they are part of the invention.

As the claims to polypeptide variants, naturally occurring allelic variants and polypeptides comprising a 30 contiguous amino acids of SEQ ID NO:2 have not been limited by function, said claims are broadly drawn to all possible polypeptides having the stated embodiments. As the specification has failed to provide a description for these genuses said description encompassing either a number of species which fall within the genus, or a detailed description of the genus, conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Therefore, the specification does not provide adequate written description to support the multitude of proteins and peptides encompassed by claims to allelic variants, polypeptides comprising variants which are at least 90% identical to SEQ ID NO:1 or 2, or isolated polypeptides comprising generic 30 residue oligomers of SEQ ID NO:2. This is insufficient to support the generic claims as provided by the Interim Written Description Guidelines published in the January 5, 2001 Federal Register at Volume 66, Number 4, pages 1099-1111.

7. Claims 6, 7 and 9 are rejected under 35 U.S.C. 102(a) as being anticipated by Accession Number LEG9_HUMAN (Database SwissProt, last sequence revision July 15, 1998).

Claim 6 is drawn to an isolated polypeptide comprising the amino acid sequences of SEQ ID NO:1 or 2. Claim 7 is drawn to an isolated polypeptide comprising a fragment of SEQ ID NO:2, said fragment consisting of at least 30 contiguous amino acids of SEQ ID NO:2. Claim 9 is drawn to a polypeptide which is 90% identical to a polypeptide comprising the amino acids of SEQ ID NO:1 or 2. Accession Number LEG9_HUMAN discloses SEQ ID NO:1 and SEQ ID NO:2, therefore meeting the limitations claims 6, 7 and 9 are met. Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

8. Claims 7 and 9 are rejected under 35 U.S.C. 102(a) as being anticipated by Matsumoto et al (Journal of Biological Chemistry, July 3, 1998, Vol. 273, pp. 16976-16984). The embodiments of claims 7 and 9 are set forth above. Matsumotot et al disclose human ecalectin, a polypeptide comprising 30 contiguous amino acid resides of SEQ ID NO:2. Ecalectin has 323 of the 355 residues of SEQ ID NO:2, therefore ecalectin is 90.9% identical to SEQ ID NO:2. Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

9. Claims 7 and 10 are rejected under 35 U.S.C. 102(e) as being anticipated by Ni et al (US 6,027,916, cited in the previous Office action). Claim 7 is drawn to an isolated polypeptide comprising at least 30 contiguous amino acids of SEQ ID NO:2. Claim 10 embodies the polypeptide of claim 7 and additional heterologous amino acid sequences. Ni et al disclose Sequence No. 4, said Sequence having 148 and 163 contiguous amino acids residues of SEQ ID NO:2. Ni et al also disclose the fusion of Sequence 4 to heterologous amino acid residues (for example column 11, line 46 to column 12, line 14).

10. Claims 7 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Tureci et al (Journal of Biological Chemistry, March 7, 1997, Vol. 272, pp. 6416-6422, cited in the previous Office action).

Tureci et al disclose the sequence of human Galectin-9, said sequence having 87, 46 and 42 contiguous animo acid residues of SEQ ID NO:2 (residues 1-87, resides 89 to 134, resides 149 to 269, and residues 271 to 312, respectively). Tureci et al disclose that residues 1-81 fused with a 6-histidine tail at the amino terminus (page 6417, first column, under "Production of His-tagged Recombinant Protein), thus disclosing a polypeptide comprising 81 amino acid residues of SEQ ID NO:2 and a heterologous amino acid sequence.

11. All other rejections and objections as stated in Paper No. 12 are withdrawn.

Conclusion

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Canella whose telephone number is (703) 308-8362. The examiner can normally be reached on Monday through Friday from 8:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Karen A. Canella, Ph.D.
Patent Examiner, Group 1642
May 20, 2002